

Applicant

Notice of Allowability**Application No.**

09/155,982

Applicant(s)

KLEIN ET AL.

Examiner

Ginny Portner

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☐ This communication is responsive to 3/25/2004 and authorization 6/9/2004 for examiner's amdt.
2. ☒ The allowed claim(s) is/are 40-48, 50-78
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☒ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☒ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☒ to Paper No./Mail Date Paper # 11/09/1998
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

REASONS FOR ALLOWANCE

1. The following is an examiner's statement of reasons for allowance: The instantly claimed isolated monoclonal antibody that is specific for the *Tylorella equigenitalis* protein 150 kDA, is not taught, nor reasonably suggested by the prior art of record. The claimed compositions all comprise the novel and unobvious embodiment of a monoclonal antibody that specifically binds to the 150 kDA protein, therefore, combination compositions, kits, and methods of use of the monoclonal antibodies also define over the prior art of record.

2. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

EXAMINER'S AMENDMENT

3. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

4. Authorization for this examiner's amendment was given in a telephone interview with Ms. Erin M. Dunston, Registration Number 51,147 on June 9, 2004.

5. The application has been amended as follows:

Please substitute the following listing of the claims.

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Claims 1-39 . Cancelled.

Claim 40. (Previously Presented) An isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment, which recognizes a 150 kDA *T. equigenitalis* protein.

Claim 41. (Currently Amended) An isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment according to claim 40, in combination with at least one antibody or Fv, Fab or F(ab')² fragment thereof which recognize *T. equigenitalis* ~~proteins~~ antigens selected from the group consisting of *T. equigenitalis* antigens ~~proteins~~ of 120 kDA, 52.7 kDA and 22 (LPS) kDA.

Claim 42. (Previously Presented) An isolated monoclonal antibody obtained by a process comprising:

fusing non-secreting murine myeloma cells with spleen cells from mice immunized against an inactivated strain of the species *T. equigenitalis* or extract(s) of such a strain,
cloning and selecting according to the capacity of their culture supernatant to recognize a 150 kDA *T. equigenitalis* protein,
recovering the required monoclonal antibody, and
optionally purifying said monoclonal antibody.

Claim 43. (Currently Amended) A method of obtaining a monoclonal antibody according to claim 40, comprising:

fusing non-secreting murine myeloma cells with spleen cells from mice immunized by means of a strain of the species *T. equigenitalis* or extract(s) from such a strain, screening hybridomas whose culture supernatants exhibit a positive reaction with a 150 kDA *T. equigenitalis* protein ~~or a fragment thereof~~,

selecting by cloning the hybridomas with respect to their reactivity, in relation to *T. equigenitalis*,

recovering the monoclonal antibody, and
optionally purifying said monoclonal antibody.

Claim 44. (Currently Amended) A strain of hybridoma, which secretes ~~a~~ the monoclonal antibody according to claim 40.

Claim 45. (Currently Amended) A method of identification of a bacterium of the species *Taylorella equigenitalis* (*T. equigenitalis*) in a specimen or in a culture comprising:

bringing the specimen or the culture to be analyzed, which may contain *T. equigenitalis* antigen, into contact with an effective quantity of a monoclonal antibody or Fv, Fab or F(ab')² fragment thereof according to claim 40, under conditions permitting a reaction of the antigen-antibody type, and

detecting any antigen/antibody type reaction product formed, wherein said product is indicative of the presence of a bacterium of the species *T. equigenitalis*.

Claim 46. (Previously Presented) A method of diagnosis of an infection by *Taylorella equigenitalis* (*T. equigenitalis*) comprising:

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(a) bringing a monoclonal antibody or fragment thereof according to claim 40, into contact with a biological sample, wherein said sample may contain *T. equigenitalis* antigen, under conditions permitting an antigen-antibody reaction, and

(b) detecting any antigen/antibody type reaction product formed in said sample between the antibody or fragment of (a) and a *T. equigenitalis* antigen, wherein said product is indicative of a diagnosis for *T. equigenitalis* infection.

Claim 47. (Previously Presented) The method according to claim 45, further comprising blocking the non antigen-antibody reactions.

Claim 48. (Previously Presented) A kit for application of a method of identification of a bacterium of the species *Taylorella equigenitalis* (*T. equigenitalis*) in a specimen or in a culture comprising:

a monoclonal antibody or fragment according to claim 40,

a reagent for detecting the intended immunologic reaction,

optionally, a reagent for blocking the non antigen-antibody reactions, and

instructions for use.

Claim 49. Cancelled.

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Claim 50. (Currently Amended) A kit according to claim 48, wherein said reagent for ~~carrying out~~ detecting the intended immunologic reaction is selected from the group consisting of markers and buffers.

Claim 51. (Previously Presented) A kit according to claim 48, wherein a reagent for blocking the non antigenic-antibody reaction is included and said reagent is mouse serum.

Claim 52. (Currently Amended) The method according to claim 47, wherein ~~the non-antigen-antibody reaction is blocked by saturation of the specimen obtained by means of a serum from which anti-*T. equigenitalis* antibodies have been removed~~ wherein the blocking comprises saturating the specimen with serum from which anti-*T. equigenitalis* antibodies have been removed.

Claim 53. (Previously Presented) The method according to claim 46, further comprising blocking the non antigen-antibody reactions.

Claim 54. (Currently Amended) An isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment according to claim 40, in combination with antibodies or Fv, Fab or F(ab')² fragments thereof which recognize *T. equigenitalis* antigens ~~proteins~~ of 120 kDA, 52.7 kDA and 22 (LPS) kDA.

Claim 55. (Previously Presented) An isolated monoclonal antibody or its Fv, Fab or F(ab')²

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fragment according to claim 40, in combination with an antibody or Fv, Fab or F(ab')² fragment thereof which recognizes a 120 kDA *T. equigenitalis* protein.

Claim 56. (Previously Presented) An isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment according to claim 40, in combination with an antibody or Fv, Fab or F(ab')² fragment thereof which recognizes a 52.7 kDA *T. equigenitalis* protein.

Claim 57. (Currently Amended) An isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment according to claim 40, in combination with an antibody or Fv, Fab or F(ab')² fragment thereof which recognizes a 22 (LPS) kDA *T. equigenitalis* ~~protein~~ antigen.

Claim 58. (Currently Amended) An isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment according to claim 42, in combination with at least one antibody or Fv, Fab or F(ab')² fragment thereof which recognizes a *T. equigenitalis* ~~protein~~-antigens selected from the group consisting of *T. equigenitalis* ~~proteins~~ antigens of 120 kDA, 52.7 kDA and 22 (LPS) kDA.

Claim 59.(Currently Amended) An isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment according to claim 42, in combination with antibodies or Fv, Fab or F(ab')² fragments thereof which recognize *T. equigenitalis* ~~proteins~~ antigens of 120 kDA, 52.7 kDA and 22 (LPS) kDA.

Claim 60. (Previously Presented) An isolated monoclonal antibody or its Fv, Fab or F(ab')²

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fragment according to claim 42, in combination with an antibody or Fv, Fab or F(ab')² fragment thereof which recognizes a 120 kDA *T. equigenitalis* protein.

Claim 61. (Previously Presented) An isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment according to claim 42, in combination with an antibody or Fv, Fab or F(ab')² fragment thereof which recognizes a 52.7 kDA *T. equigenitalis* protein.

Claim 62. (Currently Amended) An isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment according to claim 42, in combination with an antibody or Fv, Fab or F(ab')² fragment thereof which recognizes a 22 (LPS) kDA *T. equigenitalis* ~~protein~~ antigen.

Claim 63.(Previously Presented) A strain of hybridoma, which secretes the monoclonal antibody according to claim 42.

Claim 64. (Currently Amended) A method of identification of a bacterium of the species *Taylorella equigenitalis* (*T. equigenitalis*) in a specimen or in a culture comprising: bringing the specimen or the culture to be analyzed, which may contain *T. equigenitalis*, into contact with an effective quantity of the combination of an isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment which recognizes a 150 kDA *T. equigenitalis* protein and at least one antibody or Fv, Fab or F(ab')² fragment thereof which recognize *T. equigenitalis* antigen selected from the group consisting of *T. equigenitalis* antigens of 120 kDA, 52.7 kDA and 22

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(LPS) kDA according to claim 41, under conditions permitting a reaction of the antigen-antibody type, and

detecting any antigen/antibody type reaction product formed, wherein said product is indicative of the presence of a bacterium of the species *T. equigenitalis*.

Claim 65.(Currently Amended) A method of identification of a bacterium of the species *Taylorella equigenitalis* (*T. equigenitalis*) in a specimen or in a culture comprising:

bringing the specimen or the culture to be analyzed, which may contain *T. equigenitalis* antigen, into contact with an effective quantity of the monoclonal antibody or Fv, Fab or F(ab')² fragment thereof according to claim 42, under conditions permitting a reaction of the antigen-antibody type, and

detecting any antigen/antibody type reaction product formed, wherein said product is indicative of the presence of a bacterium of the species *T. equigenitalis*.

Claim 66. (Currently Amended) A method of identification of a bacterium of the species *Taylorella equigenitalis* (*T. equigenitalis*) in a specimen or in a culture comprising:

bringing the specimen or the culture to be analyzed, which may contain *T. equigenitalis*, into contact with an effective quantity of the combination of an isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment which recognizes a 150 kDA *T. equigenitalis* protein and antibodies or Fv, Fab or F(ab')² fragments thereof which recognize *T. equigenitalis* antigens of 120 kDA, 52.7 kDA and 22 (LPS) kDA ~~monoclonal antibodies or Fv, Fab or F(ab')² fragments~~

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~~thereof~~ according to claim 54 under conditions permitting a reaction of the antigen-antibody type, and

detecting any antigen/antibody type reaction product formed, wherein said product is indicative of the presence of a bacterium of the species *T. equigenitalis*.

Claim 67. (Currently Amended) A method of identification of a bacterium of the species

Taylorella equigenitalis (*T. equigenitalis*) in a specimen or in a culture comprising:

bringing the specimen or the culture to be analyzed, which may contain *T. equigenitalis*, into contact with an effective quantity of the combination of an isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment which recognizes a 150 kDa *T. equigenitalis* protein and at least one antibody or Fv, Fab or F(ab')² fragment thereof which recognizes a *T. equigenitalis* antigen selected from the group consisting of *T. equigenitalis* proteins of 120 kDa, 52.7 kDa and 22 (LPS) kDa according to claim 58 under conditions permitting a reaction of the antigen-antibody type, and

detecting any antigen/antibody type reaction product formed, wherein said product is indicative of the presence of a bacterium of the species *T. equigenitalis*.

Claim 68. (Currently Amended) A method of identification of a bacterium of the species

Taylorella equigenitalis (*T. equigenitalis*) in a specimen or in a culture comprising:

bringing the specimen or the culture to be analyzed, which may contain *T. equigenitalis*, into contact with an effective quantity of the combination of an isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment which recognizes a 150 kDa *T. equigenitalis* protein and

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antibodies or Fv, Fab or F(ab')² fragments thereof which recognize *T. equigenitalis* antigens of 120 kDA, 52.7 kDA and 22 (LPS) kDA ~~monoclonal antibodies or Fv, Fab or F(ab')² fragments thereof~~ according to claim 59 under conditions permitting a reaction of the antigen-antibody type, and

detecting any antigen/antibody type reaction product formed, wherein said product is indicative of the presence of a bacterium of the species *T. equigenitalis*.

Claim 69.(Currently Amended) A method of diagnosis of an infection by *Taylorella equigenitalis* (*T. equigenitalis*) comprising:

- (a) bringing the combination of an isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment which recognizes a 150 kDA *T. equigenitalis* protein and at least one antibody or Fv, Fab or F(ab')² fragment thereof which recognize *T. equigenitalis* antigens selected from the group consisting of *T. equigenitalis* antigens of 120 kDA, 52.7 kDA and 22(LPS) kDA a ~~monoclonal antibody or fragment thereof~~ according to claim 41 into contact with a biological sample, wherein said sample may contain *T. equigenitalis* antigen, under conditions permitting an antigen-antibody reaction, and
- (b) detecting any antigen/antibody type reaction product formed in said sample between the antibody or fragment of (a) and a *T. equigenitalis* antigen, wherein said product is indicative of a diagnosis for *T. equigenitalis* infection.

Claim 70. (Currently Amended) A method of diagnosis of an infection by *Taylorella equigenitalis* (*T. equigenitalis*) comprising:

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- (a) bringing the combination of an isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment which recognizes a 150 kDA *T. equigenitalis* protein and antibodies or Fv, Fab or F(ab')² fragments thereof which recognize *T. equigenitalis* antigens selected from the group consisting of *T. equigenitalis* antigens of 120 kDA, 52.7 kDA and 22 (LPS) kDA a monoclonal antibody or fragment thereof according to claim 42 into contact with a biological sample, wherein said sample may contain *T. equigenitalis* antigen, under conditions permitting an antigen-antibody reaction, and
- (b) detecting any antigen/antibody type reaction product formed in said sample between the antibody or fragment of (a) and a *T. equigenitalis* antigen, wherein said product is indicative of a diagnosis for *T. equigenitalis* infection.

Claim 71.(Currently Amended) A method of diagnosis of an infection by *Taylorella equigenitalis* (*T. equigenitalis*) comprising:

- (a) bringing the combination of an isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment which recognizes a 150 kDA *T. equigenitalis* protein and antibodies or Fv, Fab or F(ab')² fragments thereof which recognize *T. equigenitalis* antigens selected from the group consisting of *T. equigenitalis* proteins of 120 kDA, 52.7 kDA and 22(LPS) kDA a monoclonal antibody or fragment thereof according to claim 54 into contact with a biological sample, wherein said sample may contain *T. equigenitalis* antigen, under conditions permitting an antigen-antibody reaction, and

(b) detecting any antigen/antibody type reaction product formed in said sample between the antibody or fragment of (a) and a *T. equigenitalis* antigen, wherein said product is indicative of a diagnosis for *T. equigenitalis* infection.

Claim 72. (Currently Amended) A method of diagnosis of an infection by *Taylorella equigenitalis* (*T. equigenitalis*) comprising:

(a) bringing the combination of an isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment which recognizes a 150 kDA *T. equigenitalis* protein and at least one antibody or Fv, Fab or F(ab')² fragment thereof which recognize *T. equigenitalis* antigens selected from the group consisting of *T. equigenitalis* antigens of 120 kDA, 52.7 kDA and 22 (LPS) kDA a
~~monoclonal antibody or fragment thereof~~ according to claim 58 into contact with a biological sample, wherein said sample may contain *T. equigenitalis* antigen, under conditions permitting an antigen-antibody reaction, and

(b) detecting any antigen/antibody type reaction product formed in said sample between the antibody or fragment of (a) and a *T. equigenitalis* antigen, wherein said product is indicative of a diagnosis for *T. equigenitalis* infection.

Claim 73. (Currently Amended) A method of diagnosis of an infection by *Taylorella equigenitalis* (*T. equigenitalis*) comprising:

(a) bringing the combination of an isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment which recognizes a 150 kDA *T. equigenitalis* protein and antibodies or Fv, Fab or F(ab')² fragments thereof which recognize *T. equigenitalis* antigens of 120 kDA, 52.7

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kDA and 22 (LPS) kDA a monoclonal antibody or fragment thereof according to claim 59 into contact with a biological sample, wherein said sample may contain *T. equigenitalis* antigen, under conditions permitting an antigen-antibody reaction, and

(b) detecting any antigen/antibody type reaction product formed in said sample between the antibody or fragment of (a) and a *T. equigenitalis* antigen, wherein said product is indicative of a diagnosis for *T. equigenitalis* infection.

Claim 74.(Currently Amended) A kit for application of a method of identification of a bacterium of the species *Taylorella equigenitalis* (*T. equigenitalis*) in a specimen or in a culture comprising: the combination of isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment which recognizes a 150 kDA *T. equigenitalis* protein and at least one antibody or Fv, Fab or F(ab')² fragment thereof which recognize *T. equigenitalis* antigens selected from the groups consisting of *T. equigenitalis* proteins of 120 kDA, 52.7 kDA and 22 (LPS) kDA a monoclonal antibody or fragment according to claim 41,

reagents for detecting the intended immunologic reaction,

optionally, reagents for blocking the non antigen-antibody reactions, and

instructions for use.

Claim 75. (Previously Presented) A kit for application of a method of identification of a bacterium of the species *Taylorella equigenitalis* (*T. equigenitalis*) in a specimen or in a culture comprising:

a monoclonal antibody or fragment according to claim 42,

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reagents for detecting the intended immunologic reaction,

optionally, reagents for blocking the non antigen-antibody reactions, and instructions for use.

Claim 76. (Currently Amended) A kit for application of a method of identification of a bacterium of the species *Taylorella equigenitalis* (*T. equigenitalis*) in a specimen or in a culture comprising: the combination of isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment which recognizes a 150 kDA *T. equigenitalis* protein and antibodies or Fv, Fab or F(ab')² fragments thereof which recognize *T. equigenitalis* antigens selected from the groups consisting of *T. equigenitalis* proteins of 120 kDA, 52.7 kDA and 22 (LPS) kDA ~~a monoclonal antibody or fragment~~ according to claim 54,

reagents for detecting the intended immunologic reaction,

optionally, reagents for blocking the non antigen-antibody reactions, and instructions for use.

Claim 77. (Currently Amended) A kit for application of a method of identification of a bacterium of the species *Taylorella equigenitalis* (*T. equigenitalis*) in a specimen or in a culture comprising: the combination of isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment which recognizes a 150 kDA *T. equigenitalis* protein and at least one antibody or Fv, Fab or F(ab')² fragment thereof which recognize *T. equigenitalis* antigens selected from the group consisting of *T. equigenitalis* antigens of 120 kDA, 52.7 kDA and 22 (LPS) kDA ~~a monoclonal antibody or fragment~~ according to claim 58,

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reagents for detecting the intended immunologic reaction,
optionally, reagents for blocking the non antigen-antibody reactions, and
instructions for use.

Claim 78. (Currently Amended) A kit for application of a method of identification of a bacterium of the species *Taylorella equigenitalis* (*T. equigenitalis*) in a specimen or in a culture comprising: the combination of isolated monoclonal antibody or its Fv, Fab or F(ab')² fragment which recognizes a 150 kDA *T. equigenitalis* protein and antibodies or Fv, Fab or F(ab')² fragments thereof which recognize *T. equigenitalis* antigens selected from the group consisting of *T. equigenitalis* antigens of 120 kDA, 52.7 kDA and 22 (LPS) kDA ~~a monoclonal antibody or fragment~~ according to claim 59,

reagents, for detecting the intended immunologic reaction,
optionally, reagents for blocking the non antigen-antibody reactions, and
instructions for use.

Claims 79-83 Cancelled.

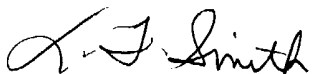
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
June 10, 2004


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